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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/155,514	11/17/1998	MIE KAINOH	1102-98	8751

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EXAMINER
SCHWADRON, RONALD B

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 03/26/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/155,514	Kainoh et al.
Examiner	**Art Unit**
Ron Schwadron	1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.

2a) ☒ This action is **FINAL.** 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *2-9, 24, 25, and 45-49* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *2-9, 24, 25, and 45-49* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/11/2002 has been entered.

2. Claims 24,25,45-49 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Gallatin et al. and prior art disclosed in the specification (see references disclosed in pages 2 and 3 of specification) for the reasons elaborated in the previous Office Action. Applicants arguments have been considered and deemed not persuasive.

Gallatin et al. teach an α integrin chain extracellular domain/Ig constant domain fusion protein (see claim 19). The specification, page 11 discloses that "chimeric protein consisting of the α chain of an integrin and the heavy or light chain of an immunoglobulin" actually means "the extracellular region of the α chain of an integrin is bound to the constant region of the heavy chain or light chain contained an immunoglobulin". A similar definition is given for "chimeric protein consisting of the β chain of an integrin and the heavy or light chain of an immunoglobulin". The art recognizes that Ig constant domains are found in light or heavy chain of an Ig molecule. Regarding claims 24 and 25, the recitation of an intended use carries no weight in the instant product claims. However, Gallatin et al. does teach pharmaceutical compositions of soluble α integrin (page 12). Gallatin et al. also teach integrin/Ig fusion proteins derived from a variety of known integrin molecules (see page 37, first paragraph). Gallatin et al. do no teach that the integrin/Ig fusion proteins contain the particular alpha or beta integrin chains recited in the claims. The prior art disclosed in the specification, pages 2 and 3 indicates that all of the integrin chains recited in the claims were known in the art. It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Gallatin et al. teach an α integrin chain extracellular domain/Ig constant domain fusion proteins, while the prior art disclosed in the specification, pages 2 and 3 indicates that all of the integrin chains recited in the claims were known in the art. One of ordinary skill in the art would have been motivated to do the aforementioned because Gallatin et al. teach integrin/Ig fusion proteins derived from a variety of known integrin molecules (see page 37, first paragraph) and that said molecules can be used in immunoassays (see page 37, first paragraph). Gallatin et al. also

teach pharmaceutical compositions containing integrin/Ig fusion proteins (see page 12, first paragraph). The amino acid sequences of the Ig heavy chain and integrins recited in the claims were known in the art.

Regarding applicants comments, Gallatin et al. teach the fusion protein can contain an intact alpha chain (see page 7, first incomplete paragraph).

3. Claims 2-9,24,25,45-49 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Carter et al. (US Patent 5,821,333) in view of Hori et al. (US Patent 5,916,771) and prior art disclosed in the specification (see references disclosed in pages 2 and 3 of specification) for the reasons elaborated in the previous Office Action. Applicants arguments have been considered and deemed not persuasive.

Carter et al. teach recombinant fusion proteins containing an adhesion molecule linked to a constant heavy chain derived from an Ig molecule (see columns 19 and 20). Carter et al. teach that such molecules can be dimers, wherein the two chains contain different adhesion molecules wherein the two adhesion molecules are both fused to heavy chain Ig constant regions (see column 19, last paragraph, continued on next page). Carter et al. do not specifically teach that the adhesion molecules are derived from an α and β chain of an integrin. Hori et al. teach that β_1 integrin molecules were known in the art as heterodimeric molecules (see column 5). The prior art disclosed in the specification, pages 2 and 3 indicates that all of the integrin chains recited in the claims were known in the art. The prior disclosed in the specification, page 3 indicates that β_1 integrin molecule was known in the art as heterodimeric molecule containing a β_1 and an $\alpha 4$ chain Carter et al. teach that Ig fusion proteins have a variety of art recognized uses (see column 4). Hori et al. teach recombinantly produced dimeric integrin molecules (see column 5). Carter et al. also teach recombinantly produced dimeric adhesion molecules (see columns 19 and 20). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Carter et al. teach recombinant fusion proteins containing an adhesion molecule linked to a constant heavy chain derived from an Ig molecule while Hori et al. teach that β_1 integrin molecules were known in the art as heterodimeric molecules and that such molecules can be recombinantly produced. One of ordinary skill in the art would have been motivated to do the aforementioned because Carter et al. teach that Ig fusion proteins have a variety of art recognized uses (see column 4). Carter et al. teach use of Ig fusion proteins as drugs (see column 4). The various integrin molecules recited in the claims were all

known in the art. Human Ig heavy chain sequences are known in the art (see Carter et al., columns 18 and 19).

Regarding applicants comments, Carter et al. teach recombinant fusion proteins containing an adhesion molecule linked to a constant heavy chain derived from an Ig molecule (see columns 19 and 20). Carter et al. teach that such molecules can be dimers, wherein the two chains contain different adhesion molecules wherein the two adhesion molecules are both fused to heavy chain Ig constant regions (see column 19, last paragraph, continued on next page). Carter et al. teach that immunoadhesions have a variety of art recognized uses (see column 4, third paragraph). Integrins are art known adhesion molecules. All of the integrin chains recited in the claims were known in the art. Carter et al. teach that immunoadhesins have a variety of art recognized uses for therapeutic and diagnostic purposes (see column 4, third paragraph). One of ordinary skill in the art would have been motivated to do have created the claimed invention in view of the cited references because Carter et al. teach that adhesion molecule/Ig fusion proteins have a variety of art recognized uses and integrins are adhesion molecules.

Regarding applicants comments about Hori et al., Hori et al. does not address the method/products of Carter et al. because Hori et al. does not disclose or deal with chimeric immunoadhesion molecules. Furthermore, Hori et al. does not address or even disclose the Carter et al. patent. Regarding claims 3 and 4 of Hori et al., said claims are drawn to a method of making an antibody (eg. not the claimed invention) and are irrelevant to the issue under consideration. The teachings of Hori et al. are relied upon in the instant rejection as disclosing that β_1 integrin molecules were known in the art as heterodimeric molecules and that such molecules can be recombinantly produced. Hori et al. does not disclose or deal with chimeric immunoadhesion molecules.

4. No claim is allowed.

5. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, THIS ACTION IS MADE FINAL even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37

CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

6. Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Papers should be faxed to Group 1600 at (703) 308-4242.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Ron Schwadron whose telephone number is (703) 308-4680. The examiner can normally be reached Monday through Thursday from 7:30 to 6:00. A message may be left on the examiners voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

RONALD B. SCHWADRON
PRIMARY EXAMINER
GROUP 1800 1600

Ron Schwadron, Ph.D.
Primary Examiner
Art Unit 1644